

REMARKS

Claims 1-4, 9-21, 24, 26, and 47-48 were pending in the application. By virtue of this response, new claim 49-53 has been added. Support for the new claim can be found throughout the specification, e.g., at pp. 24, 26, and 85-103 (Examples). As such, no new matter has been added. Accordingly, claims 1-4, 9-21, 24, 26, and 47-53 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Claim Rejections under 35 U.S.C. § 112

Claims 1-4, 9-21, 24, 26 and 47-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated immunostimulatory oligodeoxynucleic acids consisting of SEQ ID NOs:18, 38 and 59, wherein the immunostimulatory polynucleotide is fully modified phosphorothioate oligodeoxynucleotides and said immunostimulatory oligodeoxynucleic acids increase IFN-gamma or IFN-alpha and compositions comprising such and wherein the immunostimulatory nucleic acid is optionally complexed with cationic poly(lactic acid, glycolic acid) microspheres, it does not reasonably provide enablement for immunomodulatory nucleic acids, immunostimulatory nucleic acids in general, and biodegradable microcarriers in general, or oligoriboxynucleotides, immunostimulatory sequences linked to cationic poly(lactic acid, glycolic acid) by any means or biodegradable carriers in general is maintained for reasons made of record in the Office Action mailed 8-1-05.

Applicants respectfully disagree with the Examiner's contention that the claims not fully enabled for its scope. To comply fully with the enablement requirements of Section 112, first paragraph, a specification must adequately teach how to make and use the claimed invention without undue experimentation. It is the Applicants' position that, in the first instance, the Examiner has not met her initial burden of establishing a reasonable basis to question the enablement and, in the second instance, even if the Examiner had met this burden, that the claims, as amended to date, are fully enabled for its scope.

Under MPEP § 2164.04, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention in order to make a rejection. *See also, In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). As stated by the court, “it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with *acceptable evidence or reasoning* which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.” *In re Marzocchi*, 439 F.2d 220, 224 (CCPA 1971) (emphasis added).

Applicants contend that the Examiner has not met her burden of establishing that the invention as claimed is not enabled given the state of the art at the time of the filing in combination with the teachings provided in the specification. The claims, as recited, impose limitations of particular sequences. As such, the Applicants are not attempting to claim a broad area of generic immunostimulatory sequences (ISS) but rather compositions comprising an ISS of particular sequences and a length that is less than about 200 nucleotides. These limitations, in combination with the teachings in the specification for how to use the ISS, provide more than adequate guidance for one of skill in the art to be able to make the compositions that are claimed. Applicants note that these are claims directed to composition of ISS, not method claims. Accordingly, the limitations recited in the claims and the guidance in the specification fully enable one of skill in the art to practice the invention as claimed.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw this rejection.

Claim Rejections under 35 U.S.C. § 102

Claims 1-3, 15-19, 26, 48 stand rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al (US Patent No. 6800744 ('744 patent), issued October 5, 2004 with priority

to provisional document 60/051,533 filed July 2, 1997) is maintained for reasons made of record in the Office action mailed August 1, 2005.

In the Office Action mailed on August 1, 2005, the Examiner cited nucleotide residues 37-46 of SEQ ID NO: 1794 as being 100% identical to SEQ ID NO: 77 of the instant application. However, for a patent to be anticipatory under 35 U.S.C. 102(e), it must teach each and every limitation of the claim. Claim 1 (and necessarily, the claims dependent upon it) requires that the ISS be less than about 200 nucleotides in length. SEQ ID NO: 1794 of the '744 patent is 480 nucleotides long. This is more than twice the length of the recited length in claim 1. In the instant Office Action, the Examiner states that the claim recites "about" and not merely less than 200 nucleotides. However, it is highly unlikely the one of skill in the art or any entity construing the claim would construe a limitation of about 200 nucleotides to mean that it would encompass a length of 480 nucleotides.

Secondly, claim 1 (and necessarily, the claims dependent upon it) also recites that the composition comprises a pharmaceutically acceptable excipient. Nowhere in the '744 patent is there a sentence or a paragraph that teaches pharmaceutically acceptable excipient with SEQ ID NO: 1794. In fact, SEQ ID NO: 1794 (the whole 480 nucleotides or fragment of residues 37-46) is not mentioned in the specification at all. It only appears in the sequence listings in its entire 480 nucleotide listing without any calling of explicit fragments. As such, the '744 patent does not teach each and every element of the claims and therefore, cannot anticipate the claims.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882001800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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